

A DISSERTATION ON

**“TO EVALUATE EFFICACY OF LOCAL AMIKACIN  
THERAPY AS AN ADJUVANT TO PARENTRAL  
ANTIBIOTICS IN CONTROL OF SURGICAL SITE  
INFECTION COMPARED TO PARENTRAL ANTIBIOTIC  
ALONE IN A TERTIARY CARE CENTRE”**

Dissertation submitted to

**THE TAMIL NADU Dr.M.G.R.MEDICAL UNIVERISTY  
CHENNAI**

with partial fulfilment of the regulations

for the Award of the degree

**M.S. [General Surgery]**



Branch – I

**DEPARTMENT OF GENERAL SURGERY,  
STANLEY MEDICAL COLLEGE ,  
CHENNAI.**

**APRIL-2018**

## **CERTIFICATE**

This is to certify that the dissertation entitled “**TO EVALUATE EFFICACY OF LOCAL AMIKACIN THERAPY AS AN ADJUVANT TO PARENTRAL ANTIBIOTICS IN CONTROL OF SURGICAL SITE INFECTION COMPARED TO PARENTRAL ANTIBIOTIC ALONE IN A TERTIARY CARE CENTRE**” is a bonafide original work of **Dr.M. GNANA SEZHIAN** , in partial fulfilment of the requirements for M.S.Branch–I (General Surgery) Examination of the Tamil Nadu Dr. M.G.R. Medical University to be held in **APRIL 2018** under my guidance and supervision in 2017-18.

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## DECLARATION

I, **Dr. M. GNANA SEZHIAN** solemnly declare that dissertation titled, **“TO EVALUATE EFFICACY OF LOCAL AMIKACIN THERAPY AS AN ADJUVANT TO PARENTRAL ANTIBIOTICS IN CONTROL OF SURGICAL SITE INFECTION COMPARED TO PARENTRAL ANTIBIOTIC ALONE IN A TERTIARY CARE CENTRE”** is a bonafide work done by me at Govt. Stanley Medical College & Hospital during 2015-2018 under the guidance and supervision of my Unit Chief. **Prof.DR.A.K.RAJENDRAN, M.S., D.Ortho** Professor of Surgery. The dissertation is submitted to Tamil Nadu Dr. M.G.R. Medical University, towards partial fulfilment of requirement for the award of **M.S. Degree (Branch – I) in General Surgery**, Examination to be held in April 2018.

Place : Chennai.

Date :

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Title of the Work : Comparative study of Evaluate efficacy of local amikacin therapy as an adjuvant to parentral antibiotics in control of surgical site infection compared to parentral antibiotic alone in a tertiary care centre.

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**(Dr. M. GNANA SEZHIAN)**



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# **INTRODUCTION**

## INTRODUCTION

Infections that occur in the wound created by an invasive surgical procedure are generally referred to as surgical site infections (SSIs). SSIs are one of the most important causes of healthcare-associated infections (HCAIs). A prevalence survey undertaken in 2006 suggested that approximately 8% of patients in hospital in the UK have an HCAI. SSIs accounted for 14% of these infections and nearly 5% of patients who had undergone a surgical procedure were found to have developed an SSI.<sup>(1)</sup>

However, prevalence studies tend to underestimate SSI because many of these infections occur after the patient has been discharged from hospital. SSIs are associated with considerable morbidity and it has been reported that over one-third of postoperative deaths are related, at least in part, to SSI.<sup>(2)</sup>

In patients undergoing laparotomy with contaminated and dirty wounds the infection rate is 20% to 30% and 30% to 40% respectively.<sup>(3),(4)</sup>

SSIs leads to severe morbidity in the operated patient in the form of costs of treatment and prolonged hospital stay and the need for redo surgery in some cases. Most infection occur from the skin and superficial microbes and various methods can be used to tackle this condition by using this matter of fact.

Several preventive steps are followed and recommended by most of the surgical research teams and the use of local antibiotic over the wound site as an attempt to prevent the surgical site infection is one of them. A cost effective and adequately sufficient method is being studied to prevent surgical site infection through this method.

## **AIMS AND OBJECTIVES**

## **AIMS AND OBJECTIVES**

An prospective case control study

1. To analyse the effects of local antibiotic (Amikacin) therapy at the surgical site along with systemic antibiotic therapy in an attempt to prevent surgical site infections in contaminated and dirty surgical wounds as compared to that of systemic antibiotics alone.
2. Grading the SSIs in both the groups and study the effects of local antibiotic in reducing the incidence/severity of SSIs at the end of first and second week of the post operative period

# **REVIEW OF LITERATURE**

## **REVIEW OF LITERATURE**

### **Defining surgical site infection**

Postoperative wound infections, also known as surgical site infections (SSIs), complicates many surgical patients. As defined by the Centers for Disease Control and Prevention (CDC), these infections typically occur within 30 days of an operation at the site or part of the body where the surgery took place, or within a year if an implant is left in place and the infection is thought to be secondary to surgery.<sup>(5-7)</sup> SSI is now the most common and most costly hospital acquired infection.<sup>(31-33)</sup>

Since skin is normally colonised by a range of microorganisms that could cause infection, defining an SSI requires evidence of clinical signs and symptoms of infection rather than microbiological evidence alone. SSIs frequently only affect the superficial tissues, but some more serious infections affect the deeper tissues or other parts of the body manipulated during the procedure.

The majority of SSIs occurs most often between the 5th and 10th postoperative days. However, where a prosthetic implant is used, SSIs affecting the deeper tissues may occur several months after the operation.



Although the outcome measure for SSI used by many studies is based on standard definitions such as those described by the Centers for Disease Control and Prevention (CDC)<sup>(8)</sup> or the Surgical Site Infection Surveillance Service,<sup>(9)</sup> other valid measures based on clinical signs and symptoms have been described such as the Southampton<sup>(10)</sup> and ASEPSIS<sup>(11)</sup> methods.

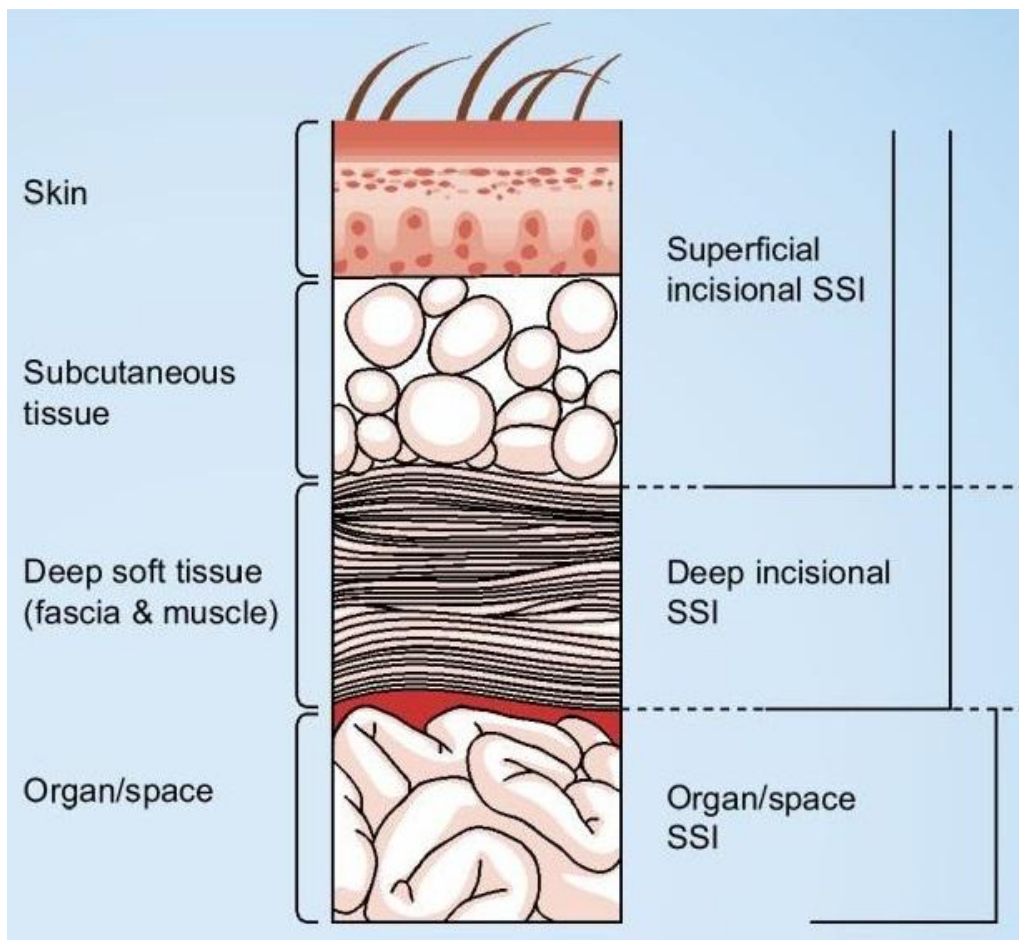


Figure 1 – different types of surgical site infections, three levels <sup>(87)</sup>

The CDC definition<sup>(12)</sup> describes three levels of SSI:

- ***superficial incisional***, affecting the skin and subcutaneous tissue. These infections may be indicated by localised (Celsian) signs such as redness, pain, heat or swelling at the site of the incision or by the drainage of pus.
- ***deep incisional***, affecting the fascial and muscle layers. These infections may be indicated by the presence of pus or an abscess, fever with tenderness of the wound, or a separation of the edges of the incision exposing the deeper tissues.
- ***organ or space infection***, which involves any part of the anatomy other than the incision that is opened or manipulated during the surgical procedure, for example joint or peritoneum.

These infections may be indicated by the drainage of pus or the formation of an abscess detected by histopathological or radiological examination or during re-operation.

In addition, there may also be microbiological evidence of wound infection from cultures obtained aseptically from wound fluid or tissue. However, since skin sites are normally colonized by a variety of organisms, positive wound cultures in the absence of clinical signs are rarely indicative of SSI. Some studies report infections that affect any part of the incision, whereas other studies focus only on those that affect the deeper tissues as these may be considered to be more important and their definition less subjective. Variation introduced by the definition of SSIs and the methods used to detect them need

to be taken account when combining or comparing evidence from different studies. This variation has been an important limiting factor in reviewing evidence for this guideline.

### **Surveillance for surgical site infection**

Surveillance of SSI provides data that can both inform and influence practice to minimise the risk of SSI, as well as communicate more clearly the risks of infection to patients.<sup>(13)</sup> Surveillance was first recognised as an important tool in reducing rates of infection in the 1980s.<sup>(14)</sup> The Study on the Efficacy of Nosocomial Infection Control (SENIC) showed that surveillance and infection control programmes that included the collection, analysis and feedback of data on infection rates to surgeons were associated with significant reductions in rates of SSI.<sup>(15)</sup>

Since then, many national surveillance systems have been established and have reported reductions in rates of SSI in association with surveillance, feedback of data to clinicians and benchmarking of rates of SSI.<sup>(9–12)</sup> Consumer demand for information about the performance of healthcare providers has also led to compulsory public reporting of data on HCAs, including SSIs.

National surveillance systems, such as the Surgical Site Infection Surveillance System in England and similar schemes in Wales and Northern

Ireland, provide standardised surveillance methods that enable hospitals to benchmark their rates of SSI.

Such benchmarking can be a powerful driver for change but requires participating hospitals to use uniform methods of finding and defining cases of SSI that are likely to reliably identify a large proportion of the infections, and a reliable approach to analysing rates of SSI that takes account of variation in risk associated with different procedures and risk factors in the patients undergoing surgery. Most national surveillance systems target surveillance towards defined groups of patients undergoing similar operative procedures, following each case up to identify those that develop an SSI, although the sensitivity of case-finding will be influenced by the methods employed.<sup>(16)</sup>

This enables rates of SSI to be calculated using the number of procedures as the denominator. Feedback of rates to individual surgical teams and comparisons with the benchmark rate are essential components of effective surveillance.<sup>(15)</sup> The risk index developed by the CDC in the USA, which takes account of the underlying illness of the patient, the duration of the operation and the wound classification of the procedure, is commonly used to adjust rates of SSI and improve the validity of comparisons where case-mix may vary over time or between centers.<sup>(17)</sup>

However, comparisons between different surveillance systems is complicated because of variation in both the methods of surveillance and the application and interpretation of case definitions.<sup>(18)</sup> Since some SSIs may take many days to develop, evidence of infection may not become apparent until after the patient has been discharged from hospital.

Surveillance focused on detecting SSI during the inpatient stay is thus likely to underestimate the true rate of SSI, a problem that is exacerbated by the increasing trend towards shorter lengths of postoperative hospital stay and day surgery.<sup>(19)</sup> Therefore, systems that enable cases of SSI to be identified after discharge from hospital enhance the value of surveillance. However, there are a number of practical difficulties in reliably identifying SSI in community settings and methods that systematically and accurately identify SSI are required if valid comparisons of rates are to be made.<sup>(20)</sup>

It is important to note that no such centralized system to report SSIs exists in our nation as of now, and it should be considered in the future to create a system to detect analyse and audit this serious post operative nosocomial complication of surgical patients

### **Risk factors**

The risk of SSI is increased by factors that:

- increase the risk of endogenous contamination (for example, procedures that involve parts of the body with a high concentration of normal flora such as the bowel)
- increase the risk of exogenous contamination (for example, prolonged operations that increase the length of time that tissues are exposed)
- diminish the efficacy of the general immune response (for example, diabetes, malnutrition, or immunosuppressive therapy with radiotherapy, chemotherapy or steroids) or local immune response (for example, foreign bodies, damaged tissue or formation of a haematoma).

Randomised controlled trials, which require the assessment of comparability between groups, have not been undertaken for risk factors.

While data on risk factors for SSI are available from observational studies using regression analyses, factors that are significant in one type of surgery may not be generalisable to other surgical procedures.

### **Age:**

Five studies were identified.<sup>(9,21–24)</sup> One prospective observational study using logistic regression to analyse data collected from 142 medical centres identified age as an independent risk factor for SSI.<sup>(21)</sup> Trained nurses gathered data on inherent and operative risk factors for SSI in patients undergoing

general and vascular surgery. Of 163 624 patients who were included in the study, 7035 developed SSI<sup>(17)</sup> within 30 days of surgery.

Patients aged over 40 had a statistically significantly increased risk of developing SSI compared with those under 40 years (OR 1.24, 95% CI 1.07 to 1.44). Another prospective observational study examined SSI in patients undergoing total hip replacement, hemiarthroplasty or revision procedures as part of SSI surveillance in England.<sup>10</sup> [EL = 2+] Trained personnel collected clinical and operative data throughout the duration of the hospital stay. Detected cases of SSI were thus classified as occurring in the immediate postoperative period.

Age over 75 was found to be a significant risk factor (compared with a baseline of age under 65) when all types of hip replacement were considered together (for age 75–79 years OR 1.56, 95% CI 1.16 to 2.10, for age  $\geq$  80 years OR 1.66, 95% CI 1.24 to 2.21).

A retrospective observational study conducted in the USA included patients who underwent general surgery with antibiotic prophylaxis at a community hospital.<sup>(22)</sup> Demographic and clinical information was extracted from the database including readmission up to 28 days post-surgery. Regression techniques were used to identify independent risk factors for SSI detected early (between 2 and 7 days postoperatively), necessitating

readmission or causing death. Age was found to be a statistically significant risk factor for early SSI incidence (SSI incidence for each decade increase in age OR 1.22,  $P < 0.01$ ).

One large prospective study ( $n = 23\,649$  wounds) including children and adults undergoing procedures on mostly clean wounds stratified results by age group<sup>(23)</sup> Observations of SSI were made for 28 days postoperatively and a broad trend of increasing SSI incidence with increasing age was reported.

A prospective cohort study of adult surgical patients ( $n = 144\,485$ ) from 11 hospitals reported an SSI incidence rate of 1.2%.<sup>24</sup> [EL = 2+] A direct linear trend of increasing risk of deep or organ space SSI from age 17 until age 65 (1.1% for each year of age,  $P < 0.002$ ) was reported. However, for patients aged over 65 the risk of SSI decreased by 1.2% for each extra year of life ( $P = 0.008$ )

## **Underlying illness**

The American Society of Anesthesiologists' (ASA) classification of physical status score is used to assess a patient's preoperative physical condition and provides a simple measure of the severity of the underlying illness. Four studies were identified that found ASA score to be an indicator of SSI development.<sup>(9,17,21,24)</sup>



A prospective cohort study of adult surgical patients ( $n = 144\,485$ ) from 11 hospitals reported an SSI incidence rate of 1.2%.<sup>24</sup> [EL = 2+] A statistically significantly higher SSI incidence for those with an ASA score of 3 or greater compared with those with an ASA score of 1 or 2 (OR 3.0, 95% CI 2.6 to 3.2) was reported.

This effect was also demonstrated in a prospective observational study examining SSI in patients undergoing total hip replacement, hemiarthroplasty or revision procedures.<sup>(9)</sup> . Cases of SSI occurring in the immediate postoperative period were included.

Overall, the SSI incidence rate was 3.07% ( $n = 24\,808$  procedures, cases of SSI = 761). Multivariate analysis showed ASA score of 3 or greater to be an independent risk factor for SSI (OR 1.55, 95% CI 1.29 to 1.88).

A prospective observational study using logistic regression to analyse data collected from patients undergoing general or vascular surgery in 142 medical centres also identified ASA score as an independent risk factor for SSI.<sup>21</sup> [EL = 2+] The SSI incidence rate was 4.3%. Compared with an ASA score of 1, a score of 3 and a score of 4 or 5 were found to be statistically significantly associated with SSI (OR 1.97, 95% CI 1.53 to 2.54 and OR 1.77, 95% CI 1.34 to 2.32, respectively).

In one retrospective observational study, analysis of data from the National Nosocomial Infections Surveillance System ( $n = 84\,691$  operations) found an overall SSI incidence of 2.8%.<sup>(17)</sup> The majority of patients (94%) were undergoing clean or clean-contaminated surgery. The strength of association between ASA score and SSI development risk was estimated (Goodman–Kruskal  $G$  statistic = 0.34, standard error (SE) = 0.01) and stratification of results by ASA score demonstrated that the rate of SSI increased by a factor of 4.7 as ASA score ranged between 1 (1.5 SSIs per 100 operations) to 5 (7.1 SSIs per 100 operations).

In addition, there are some specific underlying diseases or conditions that are independently associated with an increased risk of SSI. Surgical site infection. A number of studies in cardiac, spinal, vascular and general surgery and have shown that diabetes is strongly associated with an increased risk of SSI.<sup>(21,23,25–29)</sup> Studies report a two- to three-fold increase in risk of developing an SSI in patients with diabetes. This may be related to altered cellular immune function.

A prospective cohort study (with a parallel case–control analysis) of 1044 cardiothoracic surgery patients demonstrated evidence that the rate of SSI is independently associated with postoperative hyperglycaemia (OR 2.02, 95% CI 1.21 to 3.37) and that the risk of SSI correlated with the degree of hyperglycaemia during the postoperative period (for patients with postoperative

glucose levels of 200–249 mg/dl, 250–299 mg/dl and  $\geq 300$  mg/dl, SSI ORs were 2.54, 2.97 and 3.32, respectively).<sup>(27)</sup>

One large prospective study of procedures on mostly clean wounds in children and adults reported that malnourishment increased the incidence of SSI from 1.8% to 16.6% (univariate analysis).<sup>(23)</sup> Two studies were identified that found low serum albumin to be an indicator of SSI development.<sup>(21,22)</sup>

In a large prospective cohort study of general and vascular surgery patients ( $n = 163\ 624$  patients), multivariate analysis demonstrated that those with a low preoperative serum albumin ( $\leq 3.5$  g/dl) were more likely to develop SSI (OR 1.13, 95% CI 1.04 to 1.22), compared with those with normal serum albumin levels.<sup>(21)</sup>

The results of a retrospective observational study of patients undergoing general surgery with antibiotic prophylaxis ( $n = 9016$ ) further suggested that low serum albumin was associated with the development of SSI within the first 2–7 days postoperatively (OR 2.27,  $P < 0.01$ , per gram percent decrease).<sup>(22)</sup> One study was identified that found treatments associated with anti-cancer therapy to be indicators of SSI development.<sup>(21)</sup>

The prospective cohort of general and vascular surgery patients also found that radiotherapy within 90 days prior to surgery (OR 1.37, 95% CI 1.08

to 1.74) and use of steroids (OR 1.39, 95% CI 1.18 to 1.63) independently predicted development of SSI.<sup>(21)</sup>

## **Obesity**

Adipose tissue is poorly vascularised and the consequent effect on oxygenation of the tissues and functioning of the immune response is thought to increase the risk of SSI. In addition, operations on patients who are obese can be more complex and prolonged.<sup>(30)</sup> The effect of obesity on the risk of SSI has been investigated in cardiac and spinal surgery and in caesarean section. Studies report ORs of between 2 and 7 for SSI in patients with a body mass index of 35 kg/m<sup>2</sup> or more.<sup>(23,25–31)</sup>

## **Smoking**

The wound healing process may be affected by the vasoconstrictive effects and reduced oxygen-carrying capacity of blood associated with smoking cigarettes. Four studies were identified that investigated the association of smoking with SSI development.<sup>(21,26,29,32)</sup>

One prospective observational study, using logistic regression to analyse data collected from patients ( $n = 163\ 624$ ) undergoing general and vascular surgery in 142 medical centres, identified smoking as an independent risk factor for SSI.<sup>21</sup> [EL = 2+] Smokers had a statistically significantly greater risk of developing SSI compared with non-smokers (OR 1.23, 95% CI 1.04 to 1.22).

A case–control study of adults undergoing cardiac surgery ( $n = 117$ ) examined risk factors for SSI.<sup>29</sup> [EL = 2+] Statistically significantly more patients who developed an SSI smoked compared with uninfected controls (28.2% versus 14.1%) and, following logistic regression analysis, smoking remained an independent risk factor for SSI (OR 3.27, 95% CI 1.04 to 10.20)

A prospective observational study investigated SSI in patients undergoing breast reduction surgery.<sup>32</sup> [EL = 2+] Participants ( $n = 87$ ) were instructed to stop smoking at least 4 weeks prior to surgery. Twenty-four patients developed SSI, which occurred 8 days postoperatively on average. Statistically significantly more smokers developed SSI than non-smokers (37.2% versus 18.2%,  $P < 0.05$ ). Sixteen of 43 smokers developed SSI. Those who smoked more cigarettes were more <sup>(19)</sup> likely to develop SSI (estimated cigarettes smoked mean 146 000 range 29 200–228 125 versus mean 10 950 range 9125–54 750,  $P < 0.001$ ) and those who had smoked for a longer time also experienced statistically significantly more infections (mean pack years 20, range 4–31 versus mean pack years 2, range 1–8,  $P < 0.001$ )

A retrospective observational study of cardiac surgery ( $n = 3008$ ) investigating risk factors for SSI, using logistic regression techniques, found that smokers developed statistically significantly more sternal SSIs (OR 1.39, 95% CI 1.05 to 1.86) and deep sternal SSIs (OR 2.41, 95% CI 1.42 to 4.10) than

non-smokers and that peripheral vascular disease was also an independent risk factor for the development of deep SSI (OR 2.11, 95% CI 1.09 to 4.09).<sup>(26)</sup>

A further prospective study of cardiac surgery patients reported 199 SSIs occurring within 2345 included participants.<sup>(28)</sup> . Multivariate analysis also demonstrated that generalized peripheral vascular disease statistically significantly increased the risk of SSI (OR 1.64, 95% CI 1.16 to 2.33).

## **Wound classification**

The significance of the microbial flora normally colonising the operative site in the subsequent risk of SSI has been recognised for many decades. The wound classification developed by the

National Academy of Sciences in the 1960s distinguishes four levels of risk, from clean, where the procedure involves a sterile body site, to dirty, where the procedure involves a heavily contaminated site.

Three studies were identified that examined the association of wound classification with SSI incidence.<sup>(16,21,24)</sup> In a retrospective analysis of a large infection surveillance data set, the SSI incidence rate per 100 operations was 2.1, 3.3, 6.4, 7.1 for clean, clean-contaminated, contaminated and dirty wound classes, respectively.<sup>(17)</sup>

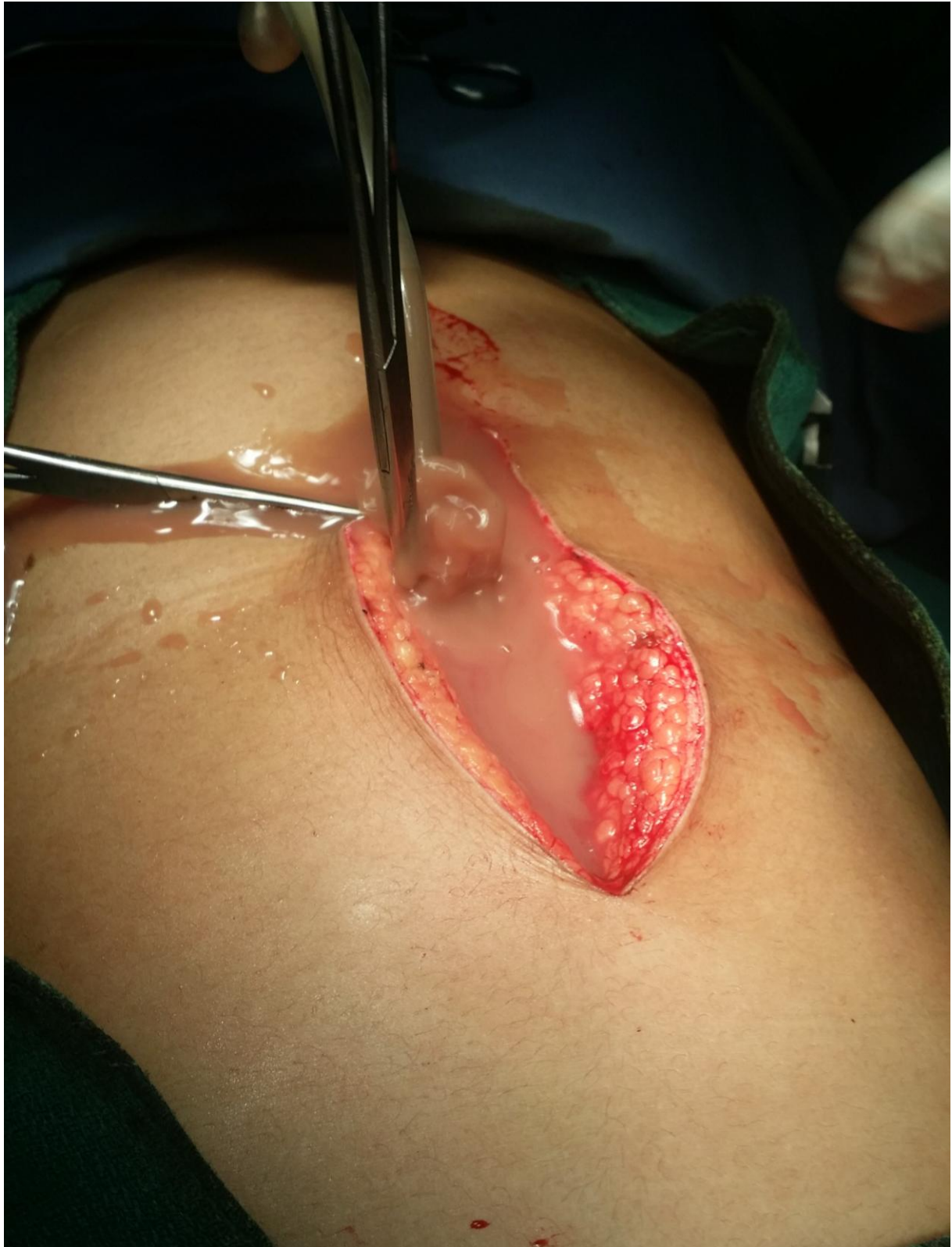


Figure 2 – per operative image during laprotomy done for pyoperitoneum, showing pus from the abdominal cavity

Another study of general and vascular procedures reported that wound class was an independent predictor of SSI (clean surgery SSI OR 1, SSI ORs for clean-contaminated, contaminated and dirty wound classes were 1.04, 1.7 and 1.5, respectively,  $P < 0.0001$ ),<sup>(21)</sup> while a third prospective study found that SSI was statistically significantly increased in contaminated and dirty wounds (wound class  $> 2$  OR 2.3, 95% CI 2.0 to 2.7).<sup>(24)</sup>

### **Site and complexity of procedure**

For many types of surgery there is evidence that the risk of SSI is affected by the specific site of the operation. Complexity of the procedure is also indicated as an SSI risk factor.

One study of general and vascular surgery estimated that there was a two- to three-fold increased risk of SSI with increasing surgical complexity measured as work relative value units.<sup>(21)</sup> However, complex surgery is more often distinguished by prolonged duration of the procedure. In studies of cardiac and hip replacement surgery,<sup>(9)</sup> there was a 1.5- to 1.75-fold increased risk of SSI associated with longer duration of surgery.

While some of these patient characteristics, such as obesity, hyperglycaemia, malnutrition and smoking, may be modified prior to surgery, others, such as the complexity of the procedure and the underlying illness in the patient, cannot. Mechanisms of accounting for variation in intrinsic



characteristics of patients or procedures that influence the risk of SSI are important for surveillance systems in order to enable valid comparisons of rates among surgeons, among hospitals, or across time. Early surveillance systems<sup>(23)</sup> used the basic wound classification to adjust for risk of SSI but analyses of large data sets on a range of operative procedures identified a few key risk factors that were associated with an increased risk of SSI and that when used in combination provided a better indicator of risk of SSI than the wound classification.<sup>(21,25)</sup>

This National Nosocomial Infection Surveillance (NNIS) system risk index is based on the presence of the following risk factors:

1. a patient with an ASA preoperative assessment score of 3, 4 or 5 (a simple measure of the severity of the patient's underlying illness)
2. an operation classified as contaminated or dirty-infected
3. an operation lasting over  $T$  hours, where  $T$  depends on the operative procedure being performed.<sup>(2,16)</sup> The  $T$  time is the 75th percentile of the distribution of operation time for a particular category of procedures rounded to the nearest hour.<sup>(17)</sup> While this NNIS risk index does not measure all the factors that contribute to the risk of developing an SSI, it does provide a practical way of adjusting rates for the major patient and operative risk factors and it is used to stratify rates of SSI by most national surveillance systems.

Other more complex risk stratification systems to predict the risk of SSI have also been developed.<sup>(21,26)</sup>

### **Evidence statements on risk factors**

#### *Age*

The age of the patient is a significant independent predictor of the risk of SSI development generally and for early SSI development.

Moreover, in adults a direct linear trend of increasing risk of SSI until age 65 has been demonstrated.

For those aged over 65, an inverse linear trend of SSI risk was found, although this finding may be subject to selection bias (i.e. only those who are fit enough undergo surgery).

#### *Underlying illness*

Those patients with an ASA score of 3 or more have a severe systemic disease and have been found to have a significantly higher risk of SSI.

Studies have repeatedly shown that diabetes is strongly associated with an increased risk of SSI.

Malnutrition has been implicated as a risk factor for SSI

There is evidence from a prospective and a retrospective study that the risk of SSI is increased in patients with a low serum albumin.

Radiotherapy and steroid use have both been linked to an increased risk of SSI.

#### *Obesity*

Studies have repeatedly shown that obesity is strongly associated with an increased risk of SSI.

### *Smoking*

Smoking, duration of smoking and number of cigarettes smoked are associated with an increased risk of SSI.

Peripheral vascular disease has been demonstrated to increase SSI risk in a prospective and a retrospective study.

### *Wound classification*

There is consistent evidence that the risk of infection increases with level of wound contamination.

## **Strategies to prevent surgical site infection:**

Now that we have analysed the factors which are risk factors for developing a surgical site infection let us go the various steps and recommendations used to prevent this complication in surgical patients.

Recommendations are categorized as either (1) basic practices that should be adopted by all acute care hospitals or (2) special approaches that can be considered for use in locations and/or populations within hospitals when HAIs are not controlled by use of basic practices.

Basic practices include recommendations where the potential to impact HAI risk clearly outweighs the potential for undesirable effects. Special approaches include recommendations where the intervention is likely to reduce HAI risk but where there is concern about the risks for undesirable outcomes resulting from the intervention, where the quality of evidence is low, or where evidence supports the impact of the intervention in select settings (eg, during outbreaks) or for select patient populations.

Hospitals can prioritize their efforts by initially focusing on implementation of the prevention approaches listed as basic practices. If HAI surveillance or other risk assessments suggest that there are ongoing .

opportunities for improvement, hospitals should then consider adopting some or all of the prevention approaches listed as special approaches. These can be implemented in specific locations or patient populations or can be implemented hospital-wide, depending on outcome data, risk assessment, and/or local requirements.

**I. Basic practices for preventing SSI: recommended for all acute care hospitals**

1. Administer antimicrobial prophylaxis according to evidence- based standards and guidelines. <sup>(34-36)</sup>

a. Begin administration within 1 hour before incision to maximize tissue concentration. <sup>(37,38)</sup> Administering agent closer than 1 hour is effective, and some studies show superior efficacy for administration between 0 and 30 minutes prior to incision compared with administration between 30 and 60 minutes. <sup>(39,40)</sup> . Two hours are allowed for the administration of vancomycin and fluoroquinolones.

b. Select appropriate agents on the basis of the surgical procedure, the most common pathogens causing SSIs for a specific procedure, and published recommendations. <sup>(38)</sup>

c. Discontinue agent within 24 hours after surgery.

Although guidelines suggest stopping the antimicrobial agent within 24 hours of surgery, there is no evidence that agents given after closure contribute to efficacy, and they do contribute to increased resistance <sup>(41,42)</sup> and the risk of *Clostridium difficile* disease.<sup>(43)</sup>

d. Adjust dosing on the basis of patient weight; for example:

i. Use 30 mg/kg for pediatric patients, 2 g of cefazolin for patients weighing 80 kg or more, and 3 g for patients weighing 120 kg or more.

ii. Vancomycin should be dosed at 15 mg/kg. Gentamicin should be dosed at 5 mg/kg for adult patients and 2.5 mg/kg for pediatric patients.

(a) For morbidly obese patients receiving gentamicin, the weight used for dose calculation should be the ideal weight plus 40% of the excess weight.

e. Redose prophylactic antimicrobial agents for long procedures and in cases with excessive blood loss during the procedure.

i. Prophylactic antimicrobials should be redosed at intervals of 2 half-lives (measured from time the preoperative dose was administered) in cases that exceed this time.

f. Use a combination of parenteral antimicrobial agents and oral antimicrobials to reduce the risk of SSI following colorectal procedures.<sup>(44-51)</sup>

*i.* The additional SSI reduction achieved with mechanical bowel preparation has not been studied, but the data supporting use of oral antimicrobials have all been generated in combination with mechanical bowel preparation.

*ii.* Mechanical bowel preparation without oral antimicrobials does not decrease the risk of SSI.

2. Do not remove hair at the operative site unless the presence of hair will interfere with the operation. Do not use razors <sup>(53)</sup>

a. If hair removal is necessary, remove hair outside the operating room using clippers or a depilatory agent.

3. Control blood glucose during the immediate postoperative period for cardiac surgery patients and noncardiac surgery patients <sup>(54-57)</sup>

a. Maintain postoperative blood glucose of 180 mg/dL or lower.

*i.* The recommendation of maintaining postoperative blood glucose less than 200 mg/dL at 6 AM on postoperative days 1 and 2 is being replaced. In 2014, this measure will be revised in the SCIP to assess glucose control (180 mg/dL or lower) in cardiac surgery patients in the time frame of 18-24 hours after anesthesia end time. Several societies, experts , and the National Quality Forum support this new recommendation. <sup>(58,59)</sup>

b. Intensive postoperative glucose control (targeting levels less than 110 mg/dL) has not been shown to reduce the risk of SSI and may

actually lead to higher rates of adverse outcomes, including stroke and death.<sup>(60)</sup>

4. Maintain normothermia (temperature of 35.5°C or more) during the perioperative period .

a. Even mild degrees of hypothermia can increase SSI rates.

Hypothermia may directly impair neutrophil function or impair it indirectly by triggering subcutaneous vasoconstriction and subsequent tissue hypoxia. In addition, hypothermia may increase blood loss, leading to wound hematomas or need for transfusion, both of which can increase rates of SSI.<sup>(61)</sup>

b. Randomized controlled trials have shown the benefits of both preoperative and intraoperative warming to reduce SSI rates and to reduce intraoperative blood loss.<sup>(62-64)</sup>

5. Optimize tissue oxygenation by administering supplemental oxygen during and immediately following surgical procedures involving mechanical ventilation

a. Supplemental oxygen is most effective when combined with additional strategies to improve tissue oxygenation, including maintenance of normothermia and appropriate volume replacement. The available evidence is in patients undergoing surgery with general anesthesia using mechanical ventilation.



*i.* Seven randomized clinical trials have been published comparing 80% with 30%-35% FiO<sub>2</sub> in patients undergoing general anesthesia with intraoperative mechanical ventilation and postoperative oxygen delivered for 2-6 hours via a nonrebreathing mask.

*ii.* Three trials in patients undergoing elective colorectal resection and 1 each in open appendectomy and total gastrectomy with esophagojejunal anastomosis reported an approximate 40% decrease in the rate of SSI. Three of the studies reported protocols that included maintenance of perioperative normothermia and liberal fluid replacement. Two trials in mixed surgical populations undergoing emergency or elective laparotomy for gastrointestinal, gynecologic, or urologic procedures reported different results.

- (a.) The large multicenter trial that restricted perioperative fluid replacement reported no difference.
- (b.) A follow-up study performed in this population noted that patients undergoing cancer surgery who received 80% FiO<sub>2</sub> had higher rates of mortality than patients undergoing cancer surgery who received 30% FiO<sub>2</sub>.
- (c.) The smaller trial without standardized protocols for perioperative normothermia or volume replacement reported an increase in SSIs. In this study, the 80% FiO<sub>2</sub> group had a significantly

higher proportion of patients with high body mass index (more than 30), higher blood loss, more crystalloid infused, and longer operations. This group also had 5 patients who remained intubated postoperatively (vs 1 in the 35 % group).

Postoperative intubation was predictive of SSI.

b. A meta-analysis of 5 of the above-referenced studies concluded that perioperative supplemental oxygen led to a relative risk (RR) reduction of 25% for SSI.

6. Use alcohol-containing preoperative skin preparatory agents if no contraindication exists.

a. Alcohol is highly bactericidal and effective for preoperative skin antisepsis but does not have persistent activity when used alone. Rapid, persistent, and cumulative antisepsis can be achieved by combining alcohol with chlorhexidine gluconate or an iodophor.

i. Alcohol is contraindicated for certain procedures, including procedures in which the preparatory agent may pool or not dry (eg, involving hair) due to fire risk. Alcohol may also be contraindicated for procedures involving mucosa, cornea, or ear.

b. The most effective disinfectant to combine with alcohol is unclear.

i. A recent trial of 849 patients undergoing clean-contaminated surgery randomized patients to preoperative skin antisepsis with chlorhexidine-alcohol or povidone-iodine.<sup>(65)</sup> The overall rate of SSI was significantly lower in the chlorhexidine-alcohol group than in the povidone-iodine group (9.5% vs 16% [ $P = .004$ ]; RR, 0.59 [95% confidence interval (CI), 0.41-0.85]).

ii. In contrast, a single-center study compared povidone-iodine followed by isopropyl alcohol versus chlorhexidine-alcohol versus iodine-alcohol using a sequential implementation design.<sup>(66)</sup> General surgical patients who received skin antisepsis with iodine-alcohol had the lowest rates of SSI (3.9 per 100 procedures), compared with 6.4 per 100 procedures for patients who received povidone-iodine followed by alcohol and 7.1 per 100 procedures for patients who received chlorhexidine-alcohol. In the absence of alcohol, chlorhexidine gluconate may have advantages over povidone-iodine, including longer residual activity and activity in the presence of blood or serum.<sup>(67)</sup>

iv. These disinfectants are not interchangeable. Follow the manufacturers' instructions to ensure correct application.

7. Use impervious plastic wound protectors for gastrointestinal and biliary tract surgery.

a. A wound protector is a plastic sheath that lines a wound and can facilitate retraction of an incision during surgery without the need for additional mechanical retractors.

b. A recent meta-analysis of 6 randomized clinical trials in 1,008 patients reported that use of a plastic wound protectors was associated with a 45% decrease in SSIs.

i. There was a nonsignificant trend toward greater protective effect using a dual-ring protector compared with a single-ring protector.

8. Use a checklist based on the World Health Organization (WHO) checklist to ensure compliance with best practices to improve surgical patient safety (quality of evidence:

a. The WHO checklist is a 19-item surgical safety checklist to improve adherence with best practices.

b. A multicenter quasi-experimental study conducted in 8 countries demonstrated that use of the WHO checklist led to lower rates of surgical complications, including SSI and death.

c. These findings have been confirmed in subsequent single-center and multicenter quasi-experimental studies.

9. Perform surveillance for SSI :

a. Identify high-risk, high-volume operative procedures to be targeted for SSI surveillance on the basis of a risk assessment of patient populations, operative procedures performed, and available SSI surveillance data.

b. Identify, collect, store, and analyze data needed for the surveillance program.

*i.* Develop a database for storing, managing, and accessing data collected on SSIs.

*ii.* Implement a system for collecting data needed to identify SSIs. Data are required from surgical and microbiological databases. Obtain the following data from surgical databases: patient name, medical record number, date, type of procedure, surgeons, anesthesiologists, incision time, wound class, ASA score, closure time, and presence of an SSI. Ideally, these data are supplemented with process data, including prophylactic agent and dose and time(s) of administration of prophylactic agent. For patients diagnosed with an SSI, necessary microbiological data include type of SSI, infecting organism and antimicrobial susceptibilities, and date of infection. More detailed surgical and patient information may be useful for some procedures, including use of general anesthesia, emergency or trauma-related surgery, body mass index, and diagnosis of diabetes.

Prepare periodic SSI reports (time frame will depend on hospital needs and volume of targeted procedures).

*iv.* Collect denominator data on all patients undergoing targeted procedures in order to calculate SSI rates for each type of procedure.

*v.* Identify trends (eg, in SSI rates and pathogens causing SSIs).

*c.* Use updated CDC NHSN definitions for SSI.

*d.* Perform indirect surveillance for targeted procedures.

*e.* Perform postoperative surveillance for 30 days; extend the postoperative surveillance period to 90 days for certain procedure categories.

*i.* Procedures that require 90-day surveillance are determined by specific procedure codes.

*f.* Surveillance should be performed on patients readmitted to the hospital.

*i.* If an SSI is diagnosed at your institution but the surgical procedure was performed elsewhere, notify the hospital where the original procedure was performed.

*g.* Develop a system for routine review and interpretation of SSI rates to detect significant increases or outbreaks and to identify areas where additional

resources might be needed to improve SSI rates. If increased rates are identified, determine the number of potentially preventable infections that occurred, defined as the number of SSIs that occurred during a procedure in which less than 100% of recommended practices and processes were completed.

## **II. Special approaches for preventing SSI**

Standard infection control methods of outbreak investigation are recommended for use in locations and/or populations within the hospital with unacceptably high SSI rates despite implementation of the basic SSI prevention strategies listed above.

1. Screen for *S. aureus* and decolonize surgical patients with an antistaphylococcal agent in the preoperative setting for high-risk procedures, including some orthopedic and cardiothoracic procedures.

- a. Screening for *S. aureus* refers to the practice of attempting to identify patients colonized with methicillin- susceptible *S. aureus* (MSSA) and/or MRSA. Decolonization refers to the practice of treating patients with known *S. aureus* colonization with antimicrobial and/or antiseptic agents to eliminate *S. aureus* colonization.

- i. There is no standardized approach to either screening or decolonizing. Most clinicians attempt to decolonize surgical

patients with a combination of chlorhexidine gluconate applied to the skin and nasal mupirocin.

b. A Cochrane review concluded that mupirocin alone may be effective, particularly in certain groups, including orthopedic and cardiothoracic patients.

Several nonrandomized trials corroborate this conclusion.

c. Clinical practice guidelines from the American Society of Health-System Pharmacists recommend giving mupirocin intranasally to all patients with documented *S. aureus* colonization for orthopedic procedures, including total joint replacement and hip fracture repair, and cardiac procedures.

d. Some trials demonstrate that preoperative screening for *S. aureus*, coupled with intranasal mupirocin and chlorhexidine bathing is effective in reducing SSI for some patients.

i. For example, a randomized, double-blind, placebocontrolled, multicenter trial that evaluated rapid identification of *S. aureus* nasal carriers followed by decolonization was associated with a greater than 2-fold reduction in the risk for postoperative infection due to *S. aureus* and an almost 5-fold reduction in risk for deep incisional SSI due to *S. aureus*.

(a) This study was performed in a setting with high baseline rates of SSI and in the absence of MRSA.



e. In contrast, other trials have failed to demonstrate a benefit.

i. A prospective, interventional cohort study with a crossover design involving 21,000 patients concluded that universal, rapid screening for MRSA at admission coupled with decolonization of carriers did not reduce the rate of SSI due to MRSA.

ii. A double-blind randomized controlled trial involving more than 4,000 patients showed that intranasal application of mupirocin, which was not coupled with chlorhexidine bathing, did not significantly reduce the *S. aureus* SSI rate.

(a) In a secondary analysis of these data, the use of intranasal mupirocin was associated with an overall decreased rate of nosocomial *S. aureus* infections among the *S. aureus* carriers.

f. A recently published meta-analysis of 17 studies concluded that decolonization strategies prevent grampositive SSIs, *S. aureus* SSIs, and MRSA SSIs, although there was significant heterogeneity among the trials.

g. Factors that impact the decision to implement screening for *S. aureus* and decolonization include adherence to basic SSI prevention strategies, baseline rate of SSI due to *S. aureus*, individual patient risk factors for acquiring SSI due to *S. aureus*, availability of resources to implement the protocol, and ability to follow-up on protocol parameters (eg, laboratory results) and adherence.

h. Routine preoperative decolonization with mupirocin without screening is not currently recommended.

i. Mupirocin resistance has been documented.

## 2. Perform antiseptic wound lavage .

a. Wound lavage is a common practice, although the solution used for lavage differs among surgeons.<sup>(68)</sup>

b. Several groups have evaluated whether dilute povidone- iodine lavage of the surgical wound can decrease the risk of SSI. A meta-analysis published in 2010 evaluated 24 randomized controlled trials and concluded that lavage with dilute povidone-iodine decreased the risk of SSI compared with nonantiseptic lavage (RR, 0.64 [95% CI, 0.51-0.82]).

## 3. Perform an SSI risk assessment,

a. Convene a multidisciplinary team (eg, surgical leadership, hospital administration, quality management services, and infection control) to identify gaps, improve performance, measure compliance, assess impact of interventions, and provide feedback.

b. Determine baseline SSI rates by surgical specialty, procedure, and/or surgeon to better target your evaluation and interventions.

4. Observe and review operating room personnel and the environment of care in the operating room.

a. Perform direct observation audits of operating room personnel to assess operating room processes and practices to identify infection control lapses, including but not limited to adherence to process measures (antimicrobial prophylaxis choice, timing and duration protocols, hair removal, etc), surgical hand antisepsis, patient skin preparation, operative technique, surgical attire (wearing and/or laundering outside the operating room), and level of operating room traffic. Perform remediation when breaches of standards are identified.

i. Operating room personnel should include surgeons, surgical technologists, anesthesiologists, circulating nurses, residents, medical students, trainees, and device manufacturer representatives.

Review instrument processing and flash sterilization logs

ii. Review maintenance records for operating room heating, ventilation, and air conditioning system, including results of temperature and relative humidity testing, and test for maintenance of positive air pressure in the operating room(s).

5. Observe and review practices in the postanesthesia care unit, surgical intensive care unit, and/or surgical ward .

- a. Perform direct observation audits of hand hygiene practices among all personnel with direct patient contact.
- b. Evaluate wound care practices.
- c. Perform direct observation audits of environmental cleaning practices.
- d. Provide feedback and review infection control measures with staff in these postoperative care settings.

### **III. Approaches that should not be considered a routine part of SSI prevention**

1. Do not routinely use vancomycin for antimicrobial prophylaxis (quality of evidence: n).

a. Vancomycin should not routinely be used for antimicrobial prophylaxis, but it can be an appropriate agent for specific scenarios. Reserve vancomycin for specific clinical circumstances, such as a proven outbreak of SSI due to MRSA; high endemic rates of SSI due to MRSA; targeted high-risk patients who are at increased risk for SSI due to MRSA (including cardiothoracic surgical patients and elderly patients with diabetes); and high-risk surgical procedures in which an implant is placed.

i. No definitions for high endemic rates of SSI due to MRSA have been established.

ii. Studies of the efficacy of vancomycin prophylaxis were published prior to the emergence of community- acquired MRSA.

b. Two meta-analyses of studies comparing glycopeptides to beta-lactam antimicrobial prophylaxis concluded that there was no difference in rates of SSI between the 2 antimicrobial prophylaxis regimens.

c. A meta-analysis of 6 studies concluded that prophylaxis with a glycopeptide and a second agent was protective against SSI due to gram-positive organisms compared with prophylaxis with a /3-lactam alone. Of note, the 2 randomized controlled trials included in the metaanalysis combined a glycopeptide with non-/3-lactam antibiotic(s). Thus, no study has prospectively analyzed

the effect of providing both glycopeptides and (3-lactam antimicrobials for preoperative antimicrobial prophylaxis. As vancomycin does not have activity against gram-negative pathogens and appears to have less activity against MSSA than /3-lactam agents, many experts recommend adding vancomycin to standard antimicrobial prophylaxis for the specific clinical circumstances described above.

2. Do not routinely delay surgery to provide parenteral nutrition.

a. Preoperative administration of total parenteral nutrition has not been shown to reduce the risk of SSI in prospective randomized controlled trials and may increase the risk of SSI.

b. Individual trials comparing enteral and parenteral perioperative nutrition and "immunomodulating" diets containing arginine and/or glutamine with "standard" control diets tend to have very small numbers and fail to show significant differences. Two recent meta-analyses, however, demonstrate reduction in postoperative infectious complication in patients receiving enteral diets containing glutamine and/or arginine administered either before or after the surgical procedure.

3. Do not routinely use antiseptic-impregnated sutures as a strategy to prevent SSIs.

a. Human volunteer studies involving foreign bodies have demonstrated that the presence of surgical sutures decreases the inoculum required to cause an SSI from  $10^6$  to  $10^2$  organisms.

b. Some trials have shown that surgical wound closure with triclosan-coated polygactin 910 antimicrobial sutures may decrease the risk of SSI compared with standard sutures. For example, a recent randomized controlled trial of 410 colorectal surgeries concluded that the

rate of SSI decreased more than 50% (9.3% in the control group vs 4.3% among cases;  $P = .05$ ).

c. In contrast, a recent systematic review and meta-analysis evaluated 7 randomized clinical trials and concluded that neither rates of SSI (odds ratio [OR], 0.77[95% CI, 0.4-1.51];  $P = .45$ ) nor rates of wound dehiscence (OR, 1.07 [95% CI, 0.21-5.43];  $P = .93$ ) were statistically different compared with controls. In addition, one small study raised concern about higher rates of wound dehiscence while using these sutures.

d. The impact of routine use of antiseptic-impregnated sutures on development of resistance to antiseptics is unknown.

#### 4. Do not routinely use antiseptic drapes as a strategy to prevent SSIs.

a. An incise drape is an adhesive film that covers the surgical incision site to minimize bacterial wound contamination due to endogenous flora. These drapes can be impregnated with antiseptic chemicals, such as iodophors.

b. A 2007 Cochrane review of 5 trials concluded that nonantiseptic incise drapes were associated with a higher risk of SSI compared with no

incise drape (RR, 1.23 [95% CI, 1.02-1.48] ), although this association may have been caused by one specific study. Two trials (abdominal and cardiac surgical patients) compared iodophor-impregnated drapes to no drapes. While wound contamination was decreased in one trial, neither trial demonstrated that iodophor-impregnated drapes decreased the rate of SSI. A nonrandomized retrospective study similarly concluded that impregnated drapes do not prevent SSIs after hernia repair.

#### IV. Unresolved issues

##### 1. Preoperative bathing with chlorhexidine-containing products.

a. Preoperative bathing with agents such as chlorhexidine has been shown to reduce bacterial colonization of the skin. Several studies have examined the utility of preoperative showers, but none has definitively proven that they decrease SSI risk.

i. To gain the maximum antiseptic effect of chlorhexidine, adequate levels of CHG must be achieved and maintained on the skin. Typically, adequate levels are achieved by allowing CHG to dry completely. New strategies for preoperative bathing with chlorhexidine, such as preimpregnated cloths, have shown promise, but data are currently insufficient to support this approach.

##### 2. Use of gentamicin-collagen sponges.



a. Gentamicin-collagen sponges have been evaluated as a way to decrease SSI among colorectal and cardiac surgical patients.

*i. Colorectal surgical patients.* Several single-center randomized trials have demonstrated that gentamicin- collagen sponges decrease the risk of SSI following colorectal procedures.<sup>(69-71)</sup> The rate of SSI was higher with the sponge, however, in a recent large, multicenter randomized clinical trial.

*ii. Cardiothoracic surgical patients.* Four randomized controlled trials have evaluated the use of gentamicin- collagen sponges in cardiothoracic surgery

Three of these trials demonstrated a decrease in SSIs,<sup>(72-74)</sup> and one showed no difference. A recent meta-analysis combining these trials concluded that the risk of deep sternal wound infection was significantly lower in patients who received a gentamicin- collagen sponge than in patients who did not (RR, 0.62 [95% CI, 0.39-0.97]) despite significant heterogeneity among the trials.<sup>186</sup>

### **USE OF LOCAL ANTIBIOTIC OVER WOUND SITE:**

Studies have shown the effectiveness of using various antiseptic solutions in the skin preparation before making the skin incision, including use of alcohol, betadine, chlorhexidine etc.<sup>(65)</sup> and the use of antiseptic wound lavage like dilute povidone iodine lavage<sup>(68)</sup> .

The use of Amikacin Sulfate as local antibiotic agent in treating Urinary tract infection as been shown in a Japanese study <sup>(76)</sup> , in which amikacin was used as bladder wash agent or renal pelvic lavage and vesical instillation.

There are studies to show the effectiveness of using antibiotic impregnated implants or prosthesis to prevent the SSIs. Study by Katsuhiro Tofuku et al. <sup>(75)</sup> showed the effectiveness of using vancomycin impregnated fibrin sealant for the prevention of surgical site infection associated with spinal instrumentation.

Study by Joseph Huh Et Al. <sup>(77)</sup> showed use of Sustained-release lipid particle-encapsulated amikacin applied to contaminated PTFE grafts increased survival and decreased postoperative graft infections. Adjunctive use of local, delayed-release antibiotics in contaminated vascular beds may allow wider clinical use of prosthetic grafts.

Amikacin also has local action at the wound site with nonspecific actions like enhancing growth of granulation tissue <sup>(78)</sup>. Study by Nandita Pal et.al. <sup>(79-82)</sup> showed that the most common organisms isolated from the surgical site infections included Staphylococcus aureus, E.Coli, Klebsiella, Pseudomonas etc <sup>(82-84)</sup> and a majority of them showed sensitivity to Inj. Amikacin (used in combination to other drugs like Cefaperazone Sulbactam or Piperazillin Tazobactum) <sup>(80-84)</sup> .

Based on these observations , the advantages of using Inj. Amikacin which showed less systemic absorption from the local wound site and sensitivity to a majority of the organisms isolated from the SSI sites and its once daily dosage, we have chosen the use of Inj. Amikacin for this study.

The Inj.,Amikacin , dosage calculated based on weight of the patient and applied on the local wound site in the subcutaneous place before the skin closure. A Feeding tube (8 or 10 Fr) is placed as a subcutaneous DT and skin closed. On POD 1 through POD 3, the same once daily dose of Amikacin is injected through the feeding tube and the tube closed. Intentionally no suction drainage is applied to the feeding tube, to prevent any additional advantage of using suction DT in subcutaneous plane as shown by review of studies done by B. Manzoor et al. <sup>(86)</sup>, that there could be some preventive effect in using subcutaneous DT in the development of SSIs.



Figure – 3: feeding tube used as Subcutaneous DT

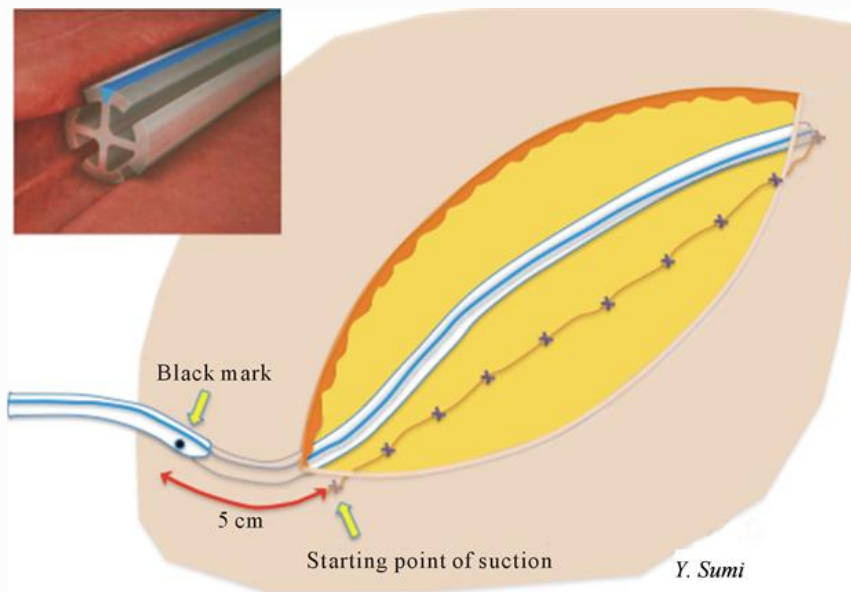


Figure - 4: image of subcutaneous DT used in appendectomy wound.

# **METHODOLOGY**

## METHODOLOGY

- 1. Type of study:** Prospective and Observational Study
- 2. Study approval:** Prior to commencement of this study - Thesis & Ethical Committee of Stanley Medical College and Hospital, Chennai had approved the thesis protocol.
- 3. Place of study:** Stanley Medical College and Hospital
- 4. Period of study:** 10 months November 2016 to August 2017
- 5. Source of data:** All cases of abdominal surgeries which falls under contaminated (classIII) and dirty (class IV) wounds like emergency laprotomies, open appendicectomies etc
- 6. Sample size:** A total of 25 cases and 25 control  
  
Study group (A): All elective and emergency surgeries of the abdomen in which local antibiotic therapy was given peroperatively & postoperatively along with systemic antibiotic

Control group (B): All cases of contaminated and dirty wounds which are matched with the cases ,who received only systemic antibiotics

## **7. Selection of patients:**

All patients operated for abdominal surgeries, both elective and emergency surgeries, which falls under class III (clean contaminated) and class IV ( dirty)

**a) Sampling method-** Purposive.

**b) Inclusion criteria-**

All cases of abdominal surgeries which falls under contaminated (classIII) and dirty (class IV) wounds like emergency laprotomies, open appendicectomies etc

**c) Exclusion criteria –**

Extremes of age <18 yrs >70 yrs

Patients on immunosuppressants, chemo/radiotherapy, steroids other serious pre-existing cardiovascular, pulmonary and immunological disease.

Uncontrolled diabetic patients

Clean (Class I) and Clean contaminated (Class II) surgical wounds

## **8. Study procedure:**

- Method of sampling was non-random, purposive.
- Ethical clearance will be obtained from the institute ethical committee
- Written informed consent will be obtained from all patients before subjecting them for the study
- All patients planned for abdominal surgeries were counseled and the procedure explained in their local language
- All patients in the group were assigned as study and corresponding matched control were selected
- The following parameters will be taken and observations will be recorded and tabulated and analyzed to achieve the objective.
- The study group patients which included cases of abdominal surgeries with class III and class IV type of wounds, peroperatively a single adult dose of Inj.Amikacin was applied over the ‘subcutaneous



cavity' of the incision site prior to skin closure. A Subcutaneous DT was kept (8 or 10 size feeding tube).

- Subsequently patient received a single daily adult dose (as per body weight) of Inj . Amikacin on the first 3 post operative days (POD 1 to POD 3).
- The Subcutaneous DT was intentionally closed without any suction drainage, to avoid confounding effecting of keeping a subcutaneous suction DT.



Figure- 5: picture showing the Subcutaneous DT kept in the laprotomy wound site

## 9. Parameters to be assessed:

- 1) Indication for surgery:
- 2) Surgical procedure done:
- 3) Type of Surgical Wound: contaminated/dirty
- 4) Systemic antibiotic used preoperatively and during immediate post operative period

### PAST HISTORY

Previous surgeries  
Diabetes Mellitus  
Others

### PERSONAL HISTORY

Alcoholic  
Smoker

### GENERAL EXAMINATION

Built  
Nourishment  
Pallor

**Incidence of Surgical site infection:** Yes/ No

If Yes - Grading of Surgical site infection as per ASEPSIS scoring

Wound characteristics	0	<20	20-39	40-59	60-79	>80
Serous Discharge	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

- ☐ Antibiotic change -10
- ☐ Drainage of pus -5
- ☐ Wound debridement -10
- ☐ Isolation of Bacteria -10
- ☐ Stay as inpatient prolonged >14 days -5

Highest Total scoring in the first week -

Highest Total scoring in the second week -

## **10. Data Analysis:**

### **Statistical methods:**

Diagnosis, total asepsis scoring, antibiotic changes at 1 week, stay as Prolonged >14days, Systemic Antibiotic used were considered as outcome variables. Case and control group were consider as primary explanatory variable. Demographic age and gender were consider as other explanatory variable.

### **Descriptive analysis:**

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

### **Quantitative outcome;**

The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. The mean differences along with their 95% CI were presented. Independent sample t-test. Association between quantitative explanatory and outcome variables was assessed by calculating person correlation coefficient and the data was represented in a scatter diagram.

**Categorical outcome:**

The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.(1)

1. Machines IB. IBM SPSS Statistics for Windows, Version 22.0. IBM Corp Armonk, NY; 2013.

# **OBSERVATIONS AND RESULTS**

## **OBSERVATIONS AND RESULTS**

The study group receives Inj. Amikacin over the wound site before skin closure and one 3 consecutive days after surgery. This is in addition to the usual Intravenous antibiotic given for all cases of laprotomy surgery.

The subsequent development of surgical site infection in this study group is compared to the control group which does not receive the additional local wound site Inj. Amikacin.

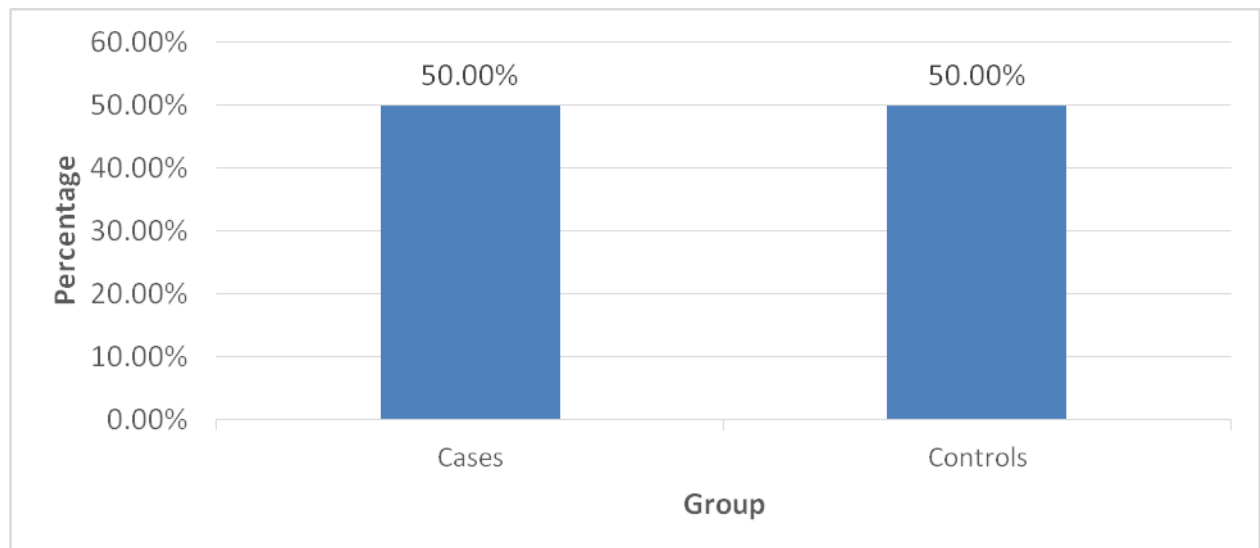
The incidence of surgical site infection and the grading (based on ASEPSIS grading) is done for the both groups for 2 weeks post operatively. The second week monitoring is to assess if there is any residual effect of adding Amikacin or any adverse effect due to its addition to the treatment regiment.

**Table 1: Descriptive analysis of group in study population (N=50)**

Group	Frequency	Percentage
Case	25	50.00%
Control	25	50.00%

Among the study population, 50% people were in case group and 50% people were in control group. (table 1 & figure 1)

**Figure 6: Bar chart of group distribution in study population (N=50)**



**Table 2: Comparison of mean age between the study groups (N=50)**

Group	AGE Mean± STD	Mean difference	95% CI		P value
			Lower	Upper	
Case	39.28 ± 14.32	-0.88	-8.77	7.01	0.824
Control	40.16 ± 13.42				

The mean age of case group was  $39.28 \pm 14.32$  and of the control group was  $40.16 \pm 13.42$ . The difference between two groups was statistically not significant (p value 0.824). (Table 2)

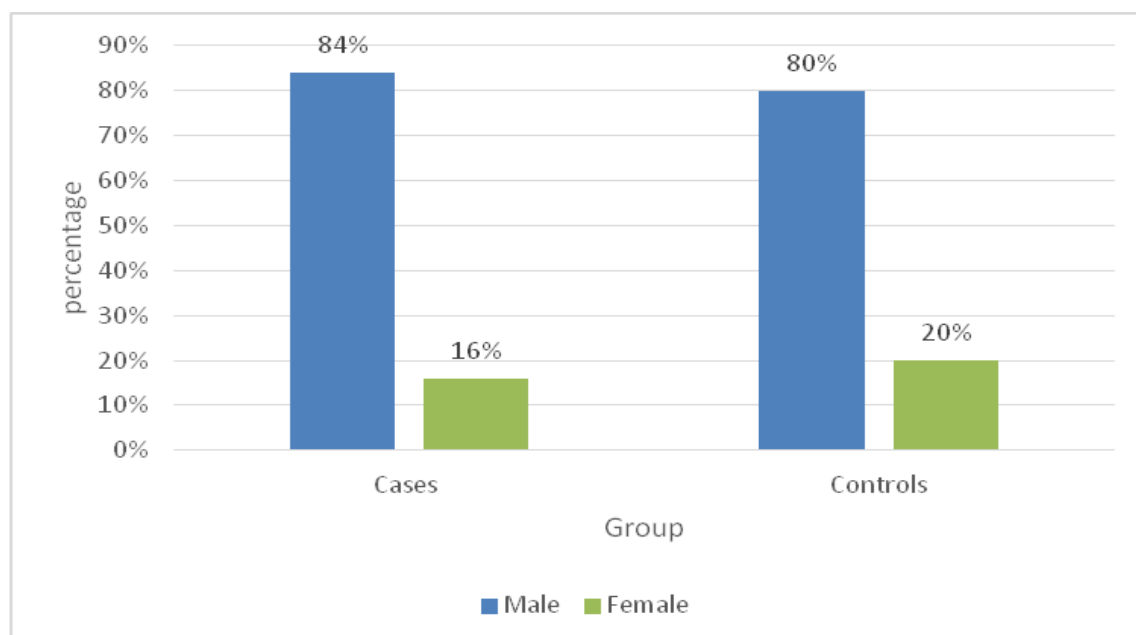


**Table 3: Association of group with gender of study population (N=50)**

Gender	Group		Chi square	P-value
	Case (N=25)	Control(N=25)		
Male	21 (84%)	20 (80%)	0.136	0.713
Female	4 (16%)	5 (20%)		

Among the case group 21 (84%) were male and 4 (16%) were female. The number of male and female participants was 20 (80%) and 5 (20%) in control group. The differences gender proportion between the two groups was statistically not significant (P value 0.713). (Table 3 & figure 2)

**Figure 7: Bar chart of comparing gender composition of the two study groups (N=50)**

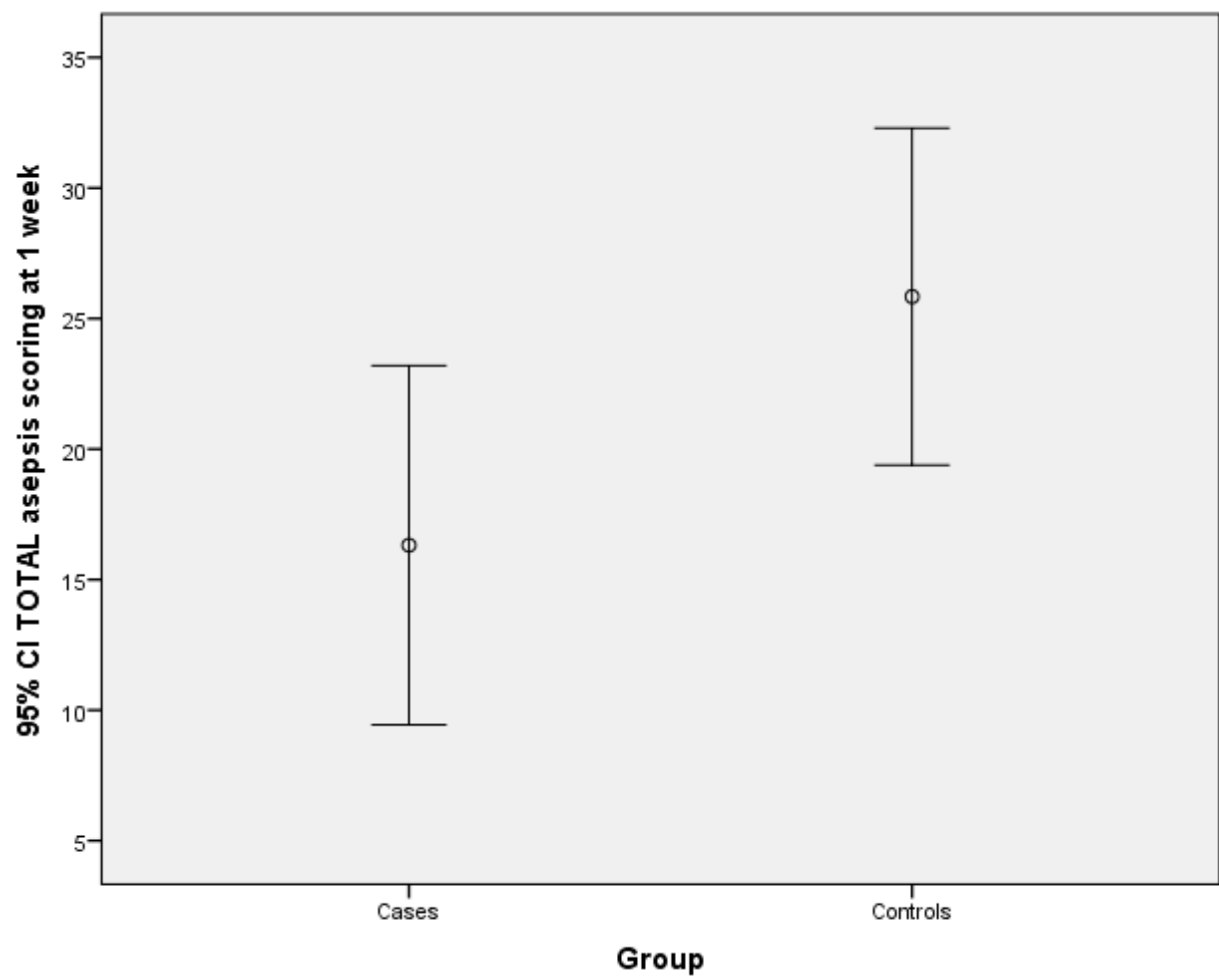


**Table 4: Comparison of mean total asepsis scoring at 1 week between study groups (N=50)**

Group	Total ASEPSIS Scoring at 1 week  Mean± STD	Mean difference	95% CI		P value
			Lower	Upper	
Case	16.32 ± 16.67	-9.52	-18.71	-0.33	0.043
Control	25.84 ± 15.64				

The mean total asepsis scoring at 1 week of case group was  $16.32 \pm 16.67$  and the control group was  $25.84 \pm 15.64$ . The difference between two groups was statistically significant (p value 0.043). (Table 4 & figure 3)

**Figure 8: Comparison of Total ASEPSIS scoring at 1 week between the two groups (N=50)**

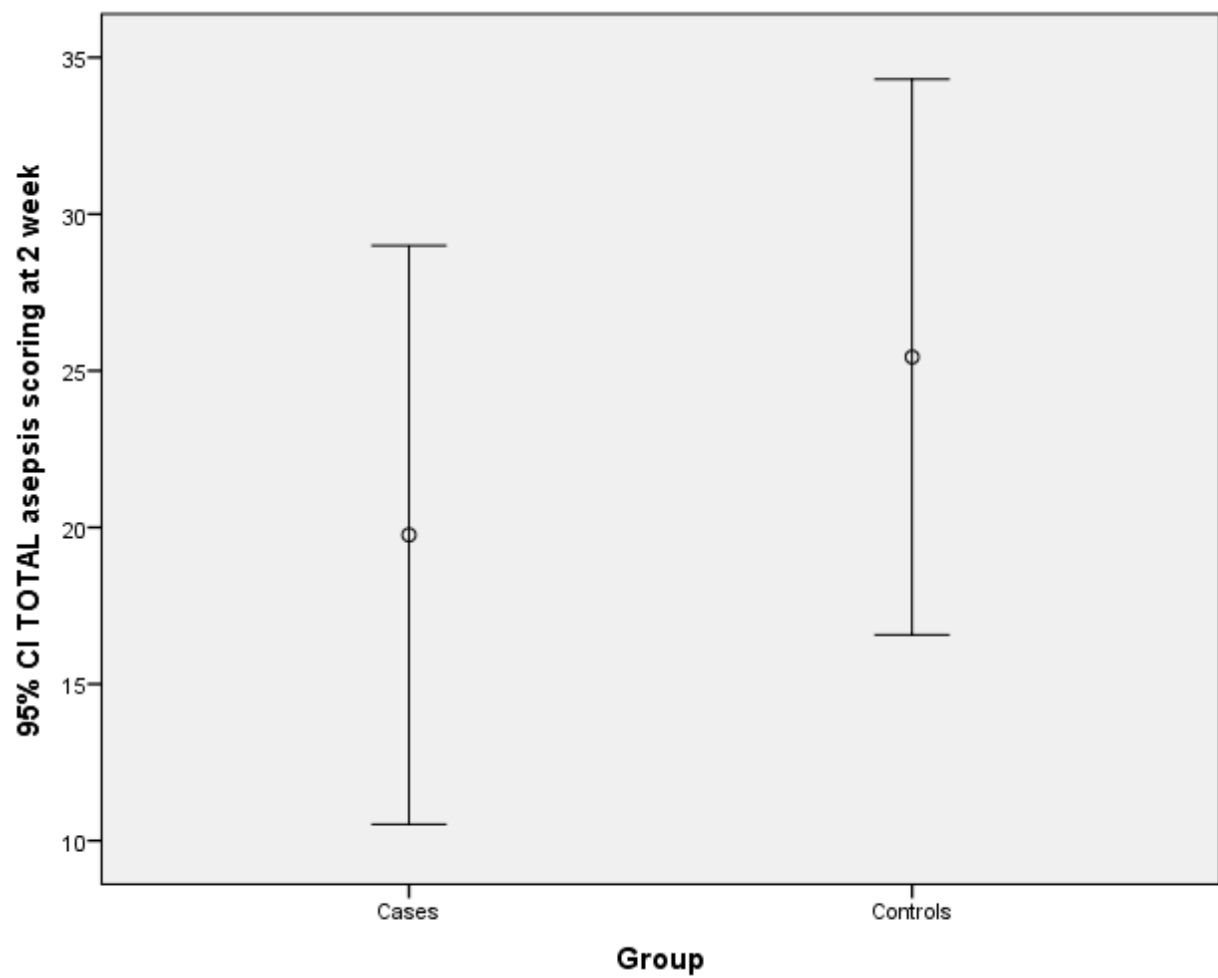


**Table 5: Comparison of mean total ASEPSIS scoring at 2 week across the two groups (N=50)**

Group	Total ASEPSIS Scoring at 2 week Mean± STD	Mean difference	95% CI		P value
			Lower	Upper	
Case	19.76 ± 22.38	-5.68	-18.15	6.79	0.365
Control	25.44 ± 21.48				

The mean total asepsis scoring at 2 week of case group was  $19.76 \pm 22.38$  and the control group was  $25.44 \pm 21.48$ . The difference between two groups was statistically not significant (p value 0.365). (Table 5 & figure 4)

**Figure 9: Comparison of Total ASEPSIS scoring at 2 week between the two study groups (N=50)**



**Table 6: Association of group with Diagnosis of study population (N= 50)**

<b>Diagnosis</b>	<b>Group</b>	
	<b>Case(N=25)</b>	<b>Control(N=25)</b>
<b>Penetrating injury abdomen</b>	2 (8%)	2 (8%)
<b>Complicated appendicitis- ileostomy</b>	1 (4%)	1 (4%)
<b>Complicated appendicitis- appendectomy</b>	6 (24%)	6 (24%)
<b>Duodenal perforation</b>	4 (16%)	4 (16%)
<b>Gastric perforation</b>	2 (8%)	2 (8%)
<b>Intestinal obstruction</b>	0 (0%)	1 (4%)
<b>Intestinal obstruction - ileostomy</b>	2 (8%)	1 (4%)
<b>Meckel's diverticulitis – resection anastomosis</b>	2 (8%)	2 (8%)
<b>Blunt injury abdomen –exploratory laparotomy</b>	3 (12%)	2 (8%)

<b>Blunt injury abdomen – resection anastomosis</b>	1 (4%)	1 (4%)
<b>Sigmoid volvulus – resection colostomy</b>	1 (4%)	1 (4%)
<b>Small bowel gangrene</b>	1 (4%)	1 (4%)
<b>Splenic cyst rupture - Splenectomy</b>	0 (0%)	1 (4%)

\*No statistical test was applied considering “0” subjects in one of the cells

Among the case group, 2 (8%) had Penetrating injury abdomen. The proportion Complicated appendicitis- ileostomy, Complicated appendicitis- appendectomy and Duodenal perforation was 1 (4%), 6 (24%) and 4 (16%) respectively. The number of Penetrating injury abdomen, Complicated appendicitis- ileostomy, Complicated appendicitis- appendectomy and Duodenal perforation was 2 (8%), 1 (4%), 6 (24%) and 4 (16%) in control group. (table 6)

**Table 7: Association of group with antibiotic changes at 1 week of study population (N=50)**

<b>Antibiotic Changes at 1 Week</b>	<b>Group</b>		<b>Chi square</b>	<b>P-value</b>
	<b>Case(N=25)</b>	<b>Control(N=25)</b>		
<b>Yes</b>	4 (16%)	13 (52%)	7.219	0.007
<b>No</b>	21 (84%)	12 (48%)		

In the case group, in 4 (16%) people antibiotic was changed at 1 week. In the control group, 13 (52%) people antibiotic was changed at 1 week. The differences antibiotic changes at 1 week proportion between the two groups was statistically significant (P value 0.007). (Table 7)



**Table 8: Association of group with Staying >14days of study population  
(N=50)**

Staying >14 days	Group		Chi square	P-value
	Case (N=25)	Control (N=25)		
<b>Yes</b>	6 (24%)	8 (32%)	0.397	0.529
<b>No</b>	19 (76%)	17 (68%)		

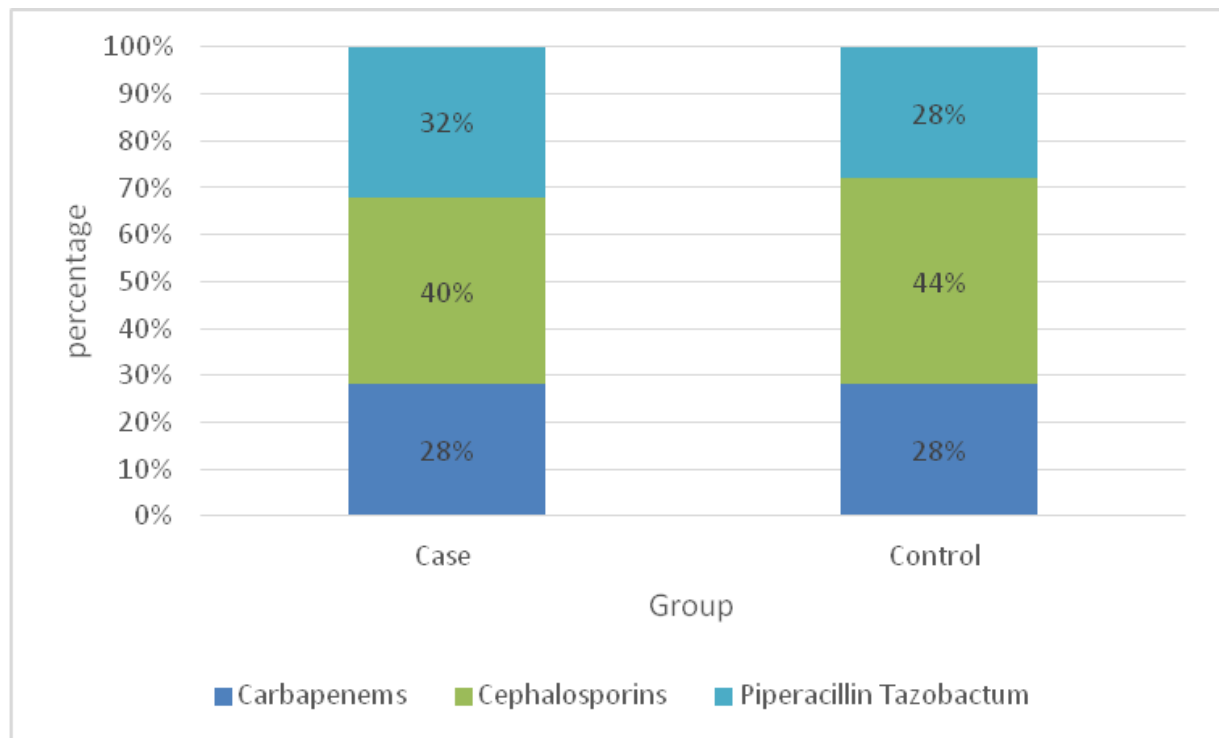
In the case group 6 (24%) patient were in hospital staying>14days. In the control group, 8 (32%) patient were in hospital staying >14days. The differences hospital staying >14days proportion between the two groups was statistically not significant (P value 0.529). (Table 8)

**Table 9: Association of group with systemic antibiotic used of study population (N=50)**

<b>Systemic Antibiotic used</b>	<b>Group</b>		<b>Chi square</b>	<b>P-value</b>
	<b>Case (N=25)</b>	<b>Control (N=25)</b>		
<b>Carbapenems</b>	7 (28%)	7 (28%)	0.114	0.944
<b>Cephalosporins</b>	10 (40%)	11 (44%)		
<b>Piperacillin Tazobactam</b>	8 (32%)	7 (28%)		

Among the case group was 7 (28%) people were using Carbapenems. The proportion Systemic Antibiotic using, Cephalosporins and Piperacillin Tazobactam was 10 (40%) and 8 (32%) respectively. The number of Systemic Antibiotic using, Carbapenems, Cephalosporins and Piperacillin Tazobactam was 7 (28%), 11 (44%) and 7 (28%) in control group. The differences Systemic Antibiotic used proportion with two groups was statically not significant (Pvalue 0.944). (Table 9 & figure 4)

**Figure 10: Bar chart of comparing Systemic Antibiotic used of the two study groups (N=50)**



# **CONCLUSION**

## CONCLUSION

This prospective, interventional and comparative study was conducted among 50 purposively selected patients who underwent abdominal surgeries categorized as dirty and contaminated wounds in the department of General Surgery, Stanley Medical College and Hospital from NOV-2016 TO AUG 2017.

The study was conducted to analyse the effectiveness of using local antibiotic over the wound site to prevent surgical site infections. The SSIs were graded using one of the standard methods of grading ASEPSIS scoring system, which grades the SSIs from 0 to 70 assessing various parameters. The scoring was done for 1<sup>st</sup> and 2<sup>nd</sup> week after surgery.

The cases and controls were sufficiently matched against age, sex, age, antibiotics used, the type of surgical diagnosis and treatment given, the type of surgical wound. Differences found to be statistically insignificant.

Subsequently the ASEPSIS scores at the end of 1<sup>st</sup> week of surgery showed that the study group patients who received the Inj. Amikacin in the local wound site showed significantly lesser grade of SSIs compared to that of the control group. The ASEPSIS score at the end of 2<sup>nd</sup> week of

surgery showed lesser grade of SSIs in the study group compared to the control though it was statistically insignificant.

The probability of antibiotic change and duration of stay in the patient was lesser in the study group though the later parameter was not statistically significant.

Hence overall conclusion is that the patients who received local wound site antibiotic (Inj.Amikacin) showed lesser grades of SSIs , more so in the 1<sup>st</sup> week of surgery and lesser need for antibiotic change and lesser duration of stay in hospital during the postoperative period compared to the control group which only received the systemic antibiotics.

## **LIMITATIONS OF THE STUDY**

Number of Limitations decrease the significance of this study

- 1) Very short duration of study
- 2) Lesser number of cases (due to unavailability during the study period)
- 3) Other associated parameters like the general condition of the patient and comorbidities were not thoroughly matched
- 4) The use of Subcutaneous DT (in spite of not being functional ) may have some positive or negative effect on the outcome

## **RECOMMENDATIONS**

Based on this prospective study, it can be proposed that use of Local application of Inj. Amikacin is a cost effective and effective method with less adverse effects in preventing surgical site infection in the immediate post operative period

It is also recommended to combine the use of a subcutaneous suction DT along with the once daily dose of Amikacin, for enhancing the preventive ability.

## MASTER CHART

S.N O	NAME	AGE/ SEX	IP NO	CASE/ CONTR OL	DIAGNOSIS	SYSTEMIC ANTIBIOTIC USED	SERO US DISC HARG E	ERYT HEM A	PURU LENT EXUD ATES	SEPA RATI ON OF DEEP TISSU ES	ANTIBI OTIC CHANG E	DRAIN AGE OF PUS	WOUN D DEBRI DEMENT	ISOLAT ION OF BACTE RIA	STAY AS INPATI ENT PROLO NGED >14 DAYS	TOTA L OUT OF 70
1.	KALLESHW ARAN	42/M	1712164	case	GANGRENO US APPENDICITI S	PIPRAZIL LIN TAZOBAC TUM	5	5	-	4	-	-	-	10	-	24
							0	0	-	4	-	-	-	-	-	4
2.	SUGANTHI	41/F	1714841	Contro l	PERFORATE D APPENDIX	PIPRAZIL LIN TAZOBAC TUM	5	5	4	4	10	5	-	10	-	43
							5	5	8	6	10	5	-	10	5	54
3.	ARUMUGAM	43/M	1714310	case	PERFORATE D APPENDICITI S	PIPRAZIL LIN TAZOBAC TUM	5	5	10	8	10	5	-	10	--	53
							5	5	10	10	10	5	-	10	5	60
4..	RENUKA	49/F	1714910	Contro l	GANGRENO US APPENDICITI S	PIPRAZIL LIN TAZOBAC TUM	5	5	10	4	10	5	-	10	-	49
							5	5	10	4	-	-	-	-	-	24
5.	VASANTHA KUMAR	17/M	1742271	CASE	PERFORATE D APPENDICITI S	CEPHALO SPORINS	-	2	-	-	-	-	-	-	-	2
							-	-	-	-	-	-	-	-	-	0
6.	VIJAYALAK SHMI	21/M	1712276	CONT ROL	GANGRENO US APPENDICITI S	CEPHALO SPORINS	2	4	-	-	10	-	-	10	-	26
							-	-	-	-	-	-	-	-	-	0
7.	RATHNAM	55/M	1733873	case	APPENDICITI S GANGRENO US ILEOTOSMY	CARBAPE NEMS	5	5	-	-	-	-	-	-	-	10
							5	5	5	2	10	-	-	10	-	37
8.	SHERMILA	35/F	1734425	Contro l	APPENDICU LAR PERFORATIO N ILEOSTOMY	CARBAPE NEMS	5	5	5	2	-	-	-	10	-	27
							5	5	5	8	10	-	-	10	5	48
9.	ROOPAVATH Y	20/F	1713264	CASE	GANGRENO US APPENDICITI S	CEPHALO SPORINS	3	3	-	-	-	-	-	-	-	6
							3	2	-	-	-	-	-	-	-	5
10	SARANYA	17/F	1714069	CASE	APPENDICU LAR	CEPHALO SPORINS	4	3	-	-	-	-	-	-	-	7



					ABSCCESS		2	-	-	-	-	-	-	-	-	2
11	MD USMAN ALI	19/M	1713548	Contro l	PERFORATE D APPENDICITIS	CEPHALO SPORINS	-	2	-	-	-	-	-	-	-	2
							3	4	6	-	-	-	-	-	-	13
12	EMMANUAL	20/M	1720012	CONT ROL	PERFORATE D APPENDICITIS	CEPHALO SPORINS	-	2	-	-	-	-	-	10	-	12
							3	4	8	10	-	-	-	-	-	25
13	RAJASEKAR AN	50/M	1715234	Case	GANGRENO US APPENDICITIS	CEPHALO SPORINS	2	3	6	-	-	-	-	-	-	11
							5	5	8	10	-	-	-	10	5	43
14	MANIKAND AN	40/M	1733714	Contro l	GANGRENO US APPENDICITIS	CEPHALO SPORINS	3	3	8	-	-	-	-	-	-	14
							4	-	2	-	-	-	-	10	-	16
15.	VINOTH KUMAR	23/M	1712250	Case	RTA RESECTION ANASTOMO SIS	CEPHALO SPORINS	5	5	-	4	-	-	-	10	-	24
							0	0	-	4	-	-	-	-	-	4
16.	MUTHU	30/M	1717280	Contro l	RTA EXPLORATO RY LAPROTOM Y	CEPHALO SPORINS	5	5	4	4	10	5	-	10	-	43
							5	5	8	6	10	5	-	10	5	54
17.	ANNAPOOR ANI	52/F	1720483	case	RTA EXPLORATO RY LAPROTOM Y	CEPHALO SPORINS	5	5	10	8	10	5	-	10	--	53
							5	5	10	10	10	5	-	10	5	60
18.	VASUDHERA N	38/M	1733713	CONT ROL	RTA HEMOPERIT ONEUM	CEPHALO SPORINS	5	5	10	4	10	5	-	-	-	39
							5	5	10	4	-	-	-	-	-	24
19.	AMIRTHA	60/F	1737502	CASE	RTA EXPLORATO RY LAPROTOM Y	CARBAPE NEMS	-	2	-	-	-	-	-	-	-	2
							-	-	-	-	-	-	-	-	-	0
20.	BALARAMA N	60/M	1730509	Contro l	RTA LAPROTOM Y RESECTION ANASTOMO SIS	CARBAPE NEMS	2	4	-	-	10	-	-	10	-	26
							-	-	-	-	-	-	-	-	-	0
21.	IRUTHAYAR AJ	34/M	1734077	Contro l	STAB INJURY RESECTION ANASTOMO SIS	CEPHALO SPORINS	5	5	-	-	-	-	-	-	-	10
							5	5	5	2	10	-	-	10	-	37
22.	JAYARAJ	24/M	1733873	Case	STAB INJURY SPLENECTO MY	CEPHALO SPORINS	5	5	5	2	-	-	-	-	-	17
							5	5	5	8	10	-	-	10	5	48
23.	ANBU	56/M	1724123	Contro	SPLENIC	CEPHALO	3	3	-	-	-	-	-	-	-	6

				1	CYST RUPTURE	SPORINS	3	2	-	-	-	-	-	-	-	5
24.	CHANDRASEKAR	43/M	1738910	Case	RTA EXPLORATORY LAPROTOMY	CEPHALOSPORINS	4	3	-	-	-	-	-	-	-	7
							2	-	-	-	-	-	-	-	-	2
25.	MOHAN RAJ	57/M	1734205	Case	ACCIDENTAL FALL BLUNT INJURY ILEOSTOMY	PIPRAZILIN TAZOBACTAM	5	5	-	4	-	-	-	10	-	24
							0	0	-	4	-	-	-	-	-	4
26.	KALTAN	50/M	1711834	Control	PENETRATING INJURY - LAPROTOMY	PIPERAZILLIN TAZOBACTAM	5	5	4	4	10	5	-	10	-	43
							5	5	8	6	10	5	-	10	5	54
27.	MANI	26/M	1734891	CASE	DU PERFORATION	PIPRAZILIN TAZOBACTAM	5	5	10	8	10	5	-	10	--	53
							5	5	10	10	10	5	-	10	5	60
28.	RAJIAH	40/M	1712355	CONTROL	DU PERFORATION	PIPRAZILIN TAZOBACTAM	5	5	10	4	10	5	-	10	-	49
							5	5	10	4	-	-	-	-	-	24
29.	DHARMAN	24/M	1729444	CASE	DU PERFORATION	CARBAPEMEMS	-	2	-	-	-	-	-	-	-	2
							-	-	-	-	-	-	-	-	-	0
30.	MANI	34/M	1729374	CONTROL	DU PERFORATION	CARBAPEMEMS	2	4	-	-	10	-	-	10	-	26
							-	-	-	-	-	-	-	-	-	0
31.	CHINNAIYAN	50/M	1736713	CASE	DU PERFORATION	CEPHALOSPORINS	5	5	-	-	-	-	-	-	-	10
							5	5	5	2	10	-	-	10	-	37
32.	KUMARAMMAL	50/F	1725833	CONTROL	DU PERFORATION	CEPHALOSPORINS	5	5	5	2	-	-	-	10	-	27
							5	5	5	8	10	-	-	10	5	48
33.	VIJAY	22/M	1736771	CONTROL	DU PERFORATION	PIPRAZILIN TAZOBACTAM	3	3	-	-	-	-	-	-	-	6
							3	2	-	-	-	-	-	-	-	5
34.	KARUPAIYA	41/M	1747662	CASE	DU PERFORATION	PIPRAZILIN TAZOBACTAM	4	3	-	-	-	-	-	-	-	7
							2	-	-	-	-	-	-	-	-	2
35.	RAVI	58/M	1738762	CASE	GASTRIC PERFORATION	CARBAPEMEMS	-	2	-	-	-	-	-	-	-	2
							3	4	6	-	-	-	-	-	-	13
36.	RAMAN	63/M	1748053	CONTROL	GASTRIC PERFORATION	CARBAPEMEMS	-	2	-	-	-	-	-	10	-	12
							3	4	8	10	-	-	-	-	-	25
37.	MANIKANDAN	43/M	1720112	CASE	GASTRIC PERFORATION	CARBAPEMEMS	2	3	6	-	-	-	-	-	-	11
							5	5	8	10	-	-	-	10	5	43
38.	MANI	45/M	1726621	CONTROL	GASTRIC PERFORATION	CARBAPEMEMS	3	3	8	-	-	-	-	-	-	14
							4	-	2	-	-	-	-	10	-	16

39.	JANAKIRAM AN	40/M	1722682	CASE	INTESTINAL OBSTRUCTION RESECTION ILEOSTOMY	PIPRAZIL LIN TAZOBACTAM	5	5	-	4	-	-	-	10	-	24
							0	0	-	4	-	-	-	-	-	4
40.	JANCY RANI	31/F	1730725	CONTROL	INTESTINAL OBSTRUCTION ADHESION LYSIS	PIPRAZIL LIN TAZOBACTAM	5	5	4	4	10	5	-	10	-	43
							5	5	8	6	10	5	-	10	5	54
41.	MUTHUPANDI	32/M	1733358	CONTROL	INTESTINAL OBSTRUCTION ILEOSTOMY	CEPHALOSPORINS	5	5	10	8	10	5	-	10	--	53
							5	5	10	10	10	5	-	10	5	60
42.	JAYARAJ	62/M	1740360	CASE	INTESTINAL OBSTRUCTION RESECTION ANASTOMOSIS	PIPRAZIL LIN TAZOBACTAM	5	5	10	4	10	5	-	-	-	39
							5	5	10	4	-	-	-	-	-	24
43.	MAHIMAIRAJ	39/M	1738762	CASE	SMV THROMBOSIS BOWEL GANGRENE	CARBAPEMEMS	-	2	-	-	-	-	-	-	-	2
							-	-	-	-	-	-	-	-	-	0
44.	MANIKANDAN	42/M	1713964	CONTROL	SMALL BOWEL GANGRENE	CARBAPEMEMS	2	4	-	-	10	-	-	10	-	26
							-	-	-	-	-	-	-	-	-	0
45.	KARTHICK	25/M	1718881	CASE	MECKEL'S DIVERTICULITIS RESECTION ANASTOMOSIS	PIPRAZIL LIN TAZOBACTAM	5	5	-	-	-	-	-	-	-	10
							5	5	5	2	10	-	-	10	-	37
46.	KANNAN	46/M	1722163	CONTROL	MECKEL'S DIVERTICULITIS RESECTION ANASTOMOSIS	PIPRAZIL LIN TAZOBACTAM	5	5	5	2	-	-	-	-	-	17
							5	5	5	8	10	-	-	10	5	48
47.	THULASIDHARAN	43/M	1736039	CASE	SIGMOID VOLVULUS RESECTION OSTOMY	CARBAPEMEMS	3	3	-	-	-	-	-	-	-	6
							3	2	-	-	-	-	-	-	-	5
48.	SOMASEKAR	70/M	1779326	CONTROL	SIGMOID VOLVULUS RESECTION OSTOMY	CARBAPEMEMS	4	3	-	-	-	-	-	-	-	7
							2	-	-	-	-	-	-	-	-	2
49.	SANTHOSH	28/M	1712072	CASE	MECKEL'S DIVERTICULITIS RESECTION ANASTOMOSIS	CEPHALOSPORINS	-	2	-	-	-	-	-	-	-	2
							-	-	-	-	-	-	-	-	-	0
50.	GANESH	36/M	1712114	CONTROL	MECKEL'S DIVERTICULITIS RESECTION ANASTOMOSIS	cephalosporins	2	4	-	-	10	-	-	10	-	26
							-	-	-	-	-	-	-	-	-	0

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## **ANNEXURE**

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## PROFORMA

### ***“Evaluate Efficacy Of Local Amikacin Therapy As An Adjuvant To Parenteral Antibiotics In Control Of Surgical Site Infection Compared To Parenteral Antibiotic Alone In A Tertiary Care Centre.”***

ஆய்வு இடத்தில் அரசு. ஸ்டான்லி மருத்துவ கல்லூரி, சென்னை  
பெயர் மற்றும் நோயாளியின் முகவரி:

நான், \_\_\_\_\_ எனது சொந்த மொழியில் ஆய்வு விவரங்களை பற்றி  
தெரிவிக்கப்பட்டது.

நான் முற்றிலும் ஆய்வு விவரங்களை புரிந்து கொண்டேன்.

ஆய்வு பங்கெடுத்துக்கொண்டுள்ள நான், சாத்தியமான அபாயங்கள் மற்றும்  
பயன்களை அறிந்து இருக்கிறேன்.

நான் எந்த நேரத்திலும் ஆய்வு இருந்து திரும்ப முடியும் மற்றும் அதன் பின்னர், நான்  
வழக்கம் போல் மருத்துவ சிகிச்சை பெற தொடரும் என்று புரிந்து கொள்ள.  
நான் இந்த ஆய்வில் பங்கு எடுத்து எந்த பணம் பெற முடியாது என்று புரிந்து.

நான் ஆட்சேபிக்கிறேன் மாட்டேன் இந்த ஆய்வின் முடிவு, எந்த மருத்துவ இதழில்  
கிடைக்கும் என்றால், என் தனிப்பட்ட அடையாள வெளிப்படவில்லை வழங்கப்படும்.

நான் இந்த ஆய்வு பகுதியாக எடுத்து செய்ய வேண்டும் என்று எனக்கு நான் இந்த  
ஆய்வு என் முழு ஒத்துழைப்பு நீட்டிக்க என்று உறுதியளிக்கிறேன்.

பெயர் மற்றும் தொண்டர் முகவரி:

தொண்டர் கையொப்பம் / பெருவிரல் ரேகை  
நாள்:

சாட்சிகள்:  
(கையொப்பம், பெயர் மற்றும் முகவரி)  
நாள்:

பெயர் மற்றும் புலன்விசாரணை கையொப்பம்: (Dr.GNANA SEZHIAN)

Name :

Age :

Sex :

IP NO:

**Indication for surgery:**

**Surgical procedure done:**

**Type of Surgical Wound: contaminated/dirty**

**Group –**

- ☐ study group (local amikacin with systemic antibiotic)

**Systemic antibiotic used:**

- Carbapenem
- Piperacillin tazobactam
- Cephalosporins

- ☐ control group (only systemic antibiotic)

Investigations	Pre-op	Post-op
Hb: TC: DC:  UREA: CREATININE: BLOOD SUGAR SR.ELECTROLYTES  LFT Proteins Albumin		

**PAST HISTORY**

Previous surgeries  
Diabetes Mellitus  
Others

**PERSONAL HISTORY**

Alcoholic  
Smoker

**GENERAL EXAMINATION**

Built  
Nourishment  
Pallor

**Incidence of Surgical site infection: Yes/ No**

If Yes - Grading of Surgical site infection as per ASEPSIS scoring

Wound characteristics	0	<20	20-39	40-59	60-79	>80
Serous Discharge	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

- ☐ Antibiotic change -10
- ☐ Drainage of pus -5
- ☐ Wound debridement -10
- ☐ Isolation of Bacteria -10
- ☐ Stay as inpatient prolonged >14 days -5

Highest Total scoring in the first week -

Highest Total scoring in the second week -